

# Vitality Training - evaluation of a group learning intervention for patients with rheumatic diseases

<b>Submission date</b> 11/07/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/10/2021	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

1.2006.3527

# Study information

## Scientific Title

Vitality Training - evaluation of a group learning intervention for patients with rheumatic diseases

## Acronym

VTP (Vitality Training Program)

## Study objectives

Participation in the Vitality Training Program will improve psychological wellbeing, coping and health related consequences of rheumatic diseases.

Please note that details pertaining to the pilot study only will be mentioned in the relevant fields with the title 'Pilot study', and details pertaining only to the main study will be mentioned with the title 'Main study'.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Pilot study: the pilot study was approved by the ethics committee on the 21st March 2001 (ref: 117-01041) with an extended approval to September 2002 (ref: 392-02-01041).
2. Main study: the National Committee for Medical Ethics in Norway approved this study on the 19th December 2006 (ref: 744-06316 1.2006.3527).

## Study design

1. Pilot study: prospective one year follow-up study (2003 to 2005)
2. Main study: randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Quality of life

## Participant information sheet

## Health condition(s) or problem(s) studied

Rheumatic diseases

## **Interventions**

Vitality Training is a ten-session program taught in groups with eight to ten participants. The whole program lasts for approximately four months with a booster session six months after the end of the program. Each session, lasting for four hours, addresses a specific theme, like: if the body could talk., relation to self and others, what gives and take energy, anger, joy, sorrow and values and choices.

Through participation-based teaching and counseling methods patients are invited to become more aware of the relationship between thoughts, feelings and bodily reactions, and further to explore own resources and potentials; with the emphasis on coping with current life situation. Exercises include awareness and relaxation training, guided imagery, moving to music, creative drawing, use of metaphors, free writing, sharing and listening to one other in small groups and homework.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

1. Psychological Distress (General Health Questionnaire 20), this will be measured repeatedly five times before the intervention, five times after the intervention and five times one year after the intervention
2. Self-Efficacy (Arthritis Self-Efficacy Scale), this will be measured one time before the intervention (baseline), one time immediately after the intervention and at one year follow-up (12 months after baseline)
3. Emotional Approach Coping (Emotional Approach Coping Scale), this will be measured one time before the intervention (baseline), one time immediately after the intervention and at one year follow-up (12 months after baseline)

## **Secondary outcome measures**

Symptoms: pain, fatigue, disease activity (Visual Analogue Score [VAS]-scales), this will be measured repeatedly five times before the intervention, five times after the intervention and five times one year after the intervention.

Additionally, patient characteristics of age, gender, civil status, work status, diagnosis, disease duration, drug use and use of health care will be collected at baseline. All data will be collected by self-reported questionnaires.

## **Overall study start date**

30/04/2007

## **Completion date**

31/05/2010

## **Eligibility**

### **Key inclusion criteria**

1. Pilot study:
  - 1.1. Patients with rheumatic diseases
  - 1.2. Aged 20 to 70
  - 1.3. Minimum disease duration one year
2. Main study:
  - 2.1. Patients with inflammatory rheumatic diseases
  - 2.2. Age 20 to 65
  - 2.3. Minimum disease duration one year

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

160

**Total final enrolment**

73

**Key exclusion criteria**

1. Pilot study: not speaking Norwegian language
2. Main study:
  - 2.1. Not speaking Norwegian language
  - 2.2. Non-inflammatory diagnosis

**Date of first enrolment**

30/04/2007

**Date of final enrolment**

31/05/2010

**Locations****Countries of recruitment**

Norway

**Study participating centre**

National Resource Center for Rehabilitation in Rheumatology

Oslo

Norway

0592

# Sponsor information

## Organisation

National Resource Center for Rehabilitation in Rheumatology (Norway)

## Sponsor details

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## Sponsor type

Hospital/treatment centre

## Website

<http://www.nrrk.diakonsyk.no>

## ROR

<https://ror.org/02jvh3a15>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

National Resource Center for Rehabilitation in Rheumatology (Norway)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		20/12/2011	29/10/2021	Yes	No